

Quality Assurance Program For Hospital Based Point of Care Testing



JOHNS HOPKINS
M E D I C I N E

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Pathology Manager, QA Specialist

Disclosures

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- Financial – Honorarium – Author for AAFP POL Insight 2015A: Quality Assurance Program for Physician Office Laboratories
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Objectives

At the end of the session, participants will be able to:

- Develop a QA program for the testing performed
- Monitor the performance of point of care tests
- Assure appropriate training of clinical staff
- Utilize various tools to monitor and assess quality

Johns Hopkins Medicine



List of Current POCT

- ACT-LR, ACT Plus
- Specific Gravity
- Creatinine
- INR
- Hgb
- Urine HCG
- Urinalysis
- HBA1c
- Glucose, whole blood
- O2 Saturation
- pH
- Strep A
- Rapid HIV 1/2 Antibody
- Rapid HCV
- Urine Drug Screen
- PPM (Fern, KOH, Sperm-Qual, Postcoital mucus, Urine Sediment)
- Tear Osmolality
- Fecal Occult Blood

Importance of POCT

- Impact on Patient Centered Care
- Potential for faster patient treatment
- Inpatient and Outpatient Testing
- Enhance achievement of national quality benchmarks
- Connectivity – data analysis, quality oversight, standardization/harmonization



Ongoing Monitoring

- Mock inspections and intracycle monitors
 - Follow regulatory body checklist
- Enroll in a CLIA approved Proficiency Testing Program
- Perform semi-annual patient correlations
- Hopkins Event Reporting Online (HERO) - submit lab issues and other patient safety concerns
- Safety Officers program/CUSP
 - Safety officers are engaged in the unit practices. Safety Officers include nurses, medical assistants, unit managers, providers



Ongoing Monitoring

- Schedule internal audits or inspections to each unit
 - Inspect all storage areas where POC supplies are kept
 - Look for open and expiration dates on all POC containers and/or test kit/devices
- Observe testing and sample collection techniques
- Review all quality control and patient documents
- Inspect devices/instruments
- Interact with testing personnel on a regular basis

Ongoing Monitoring

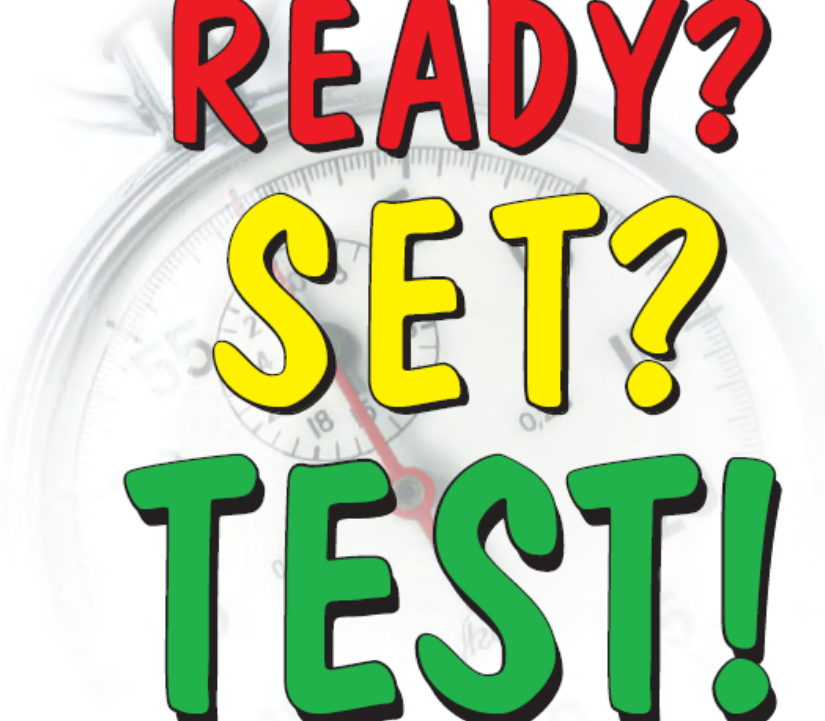
- Host a monthly meeting with the major lab vendors such as Quest, Lab Corp and Johns Hopkins Medical Lab
 - Review cancellation reports
 - Trends in cancel reasons
 - Education
 - Supplies
 - Courier schedules
 - New Test Codes
 - New Specimen Collection Devices

Developing a QA Program

- ✓ Waived
- ✓ Moderate Complexity
- ✓ Provider Performed Microscopy
- ✓ High Complexity

CLIA Expectations - Waived

- Enroll in the CLIA program;
- Pay applicable certificate fees biennially
- Follow manufacturers' test instructions
- Allow CLIA inspections
 - Collect information on waived tests;
 - Determine if a laboratory is testing outside their certificate
 - Investigate an alleged complaint
 - Determine if the performance of such tests poses a situation of immediate jeopardy

An analog clock is visible in the background, with the hands pointing to approximately 10:10. The clock face is white with black markings and numbers.

READY?
SET?
TEST!

**PATIENT TESTING
IS IMPORTANT.**

Get the right results.

<http://wwwn.cdc.gov/cli/Resouces/WaivedTests/>

Office of Surveillance, Epidemiology, and Laboratory Services
Laboratory Science, Policy, and Practice Program Office



CLIA Expectations – PPM & Moderate Complex

- Moderate
 - Same as waived criteria
 - Documented competency and training
 - Documented highest level of education
- PPM – only providers can perform
 - CAP, TJC and COLA – specific standards to follow
 - PT not required, alternative assessment allowed, at least twice per year

http://wwwn.cdc.gov/clia/Resources/PPMP/pdf/15_258020-A_Stang_PPMP_Booklet_FINAL.pdf



PROVIDER- PERFORMED MICROSCOPY PROCEDURES

A Focus on Quality Practices

<http://www.cdc.gov/clia/Resources/PPMP>

Center for Surveillance, Epidemiology, and Laboratory Services
Division of Laboratory Systems





Ambulatory QA Plan

Details from an Ambulatory Laboratory QA Plan

Staff Training and Competency Ambulatory

- New Hire training during orientation
- Annual competency checklists and/or computer based training (CBT)
- Quiz
- QC performance at least once a year
- 2 of the 6 key CLIA elements – Waived
- 6 key CLIA elements – Moderate
- Technical, supervisory and testing personnel requirements

*Key is engaging testing personnel



Vendor support/ training Ambulatory

- Utilizing Vendor Reps for support in training
- Vendor reps are brought into sites to perform on site training with our competency checklist
- Vendor reps have a great report with sites and reach out several times a year for support

Proficiency Testing Ambulatory



- Example of failed proficiency leading to investigation of POC device
 - Corrective action plan – repeat sample, vendor representative training with competency checklist, correlation samples, Technical service rep download data and evaluate
 - As a result of failed QA specimens, we isolated one Afinion, the device that we use to measure HBA1c, needed to be replaced
- HBA1c, Hgb, Strep A, pH, fecal occult blood, glucose

Quality Control Testing Ambulatory

- Documenting internal and external controls
- Follow manufacturers instructions in package inserts
- State and Federal guidelines
- External QC materials often made by company that does not make test kits
- IQCP and risk assessment

Example of EMR documentation

POCT hCG, Urine, Qualitative

	Range	3wk ago
 POC HCG, Urine	Negative	Positive
 POC QC Performed?		Yes
Resulting Agency		

- Internal QC documented with each POC test entered into patient chart
- Example is from manual test entry where interface is not in place

Example of Paper Logs

Johns Hopkins Community Physicians
 SITE _____

QuickVue One Step hCG Urine Pregnancy Test Control Log
 External Controls are done with Each New Lot # and Each New Shipment

<i>Date</i>	Kit Lot Number	Kit Expiration Date	POSITIVE CONTROL: (POS)		NEGATIVE CONTROL: (NEG)		SIGNATURE	Problems? (Y/N) if Yes document below*
			Lot #: _____ Exp Date: _____		Lot #: _____ Exp Date: _____			

DATE	PROBLEM	ACTIONS

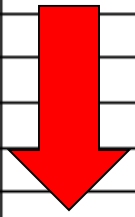
Actions include but are not limited to: re-testing the specimen with a new kit; using a kit from a new box; using a new lot number; informing manager □

Example of Paper Logs

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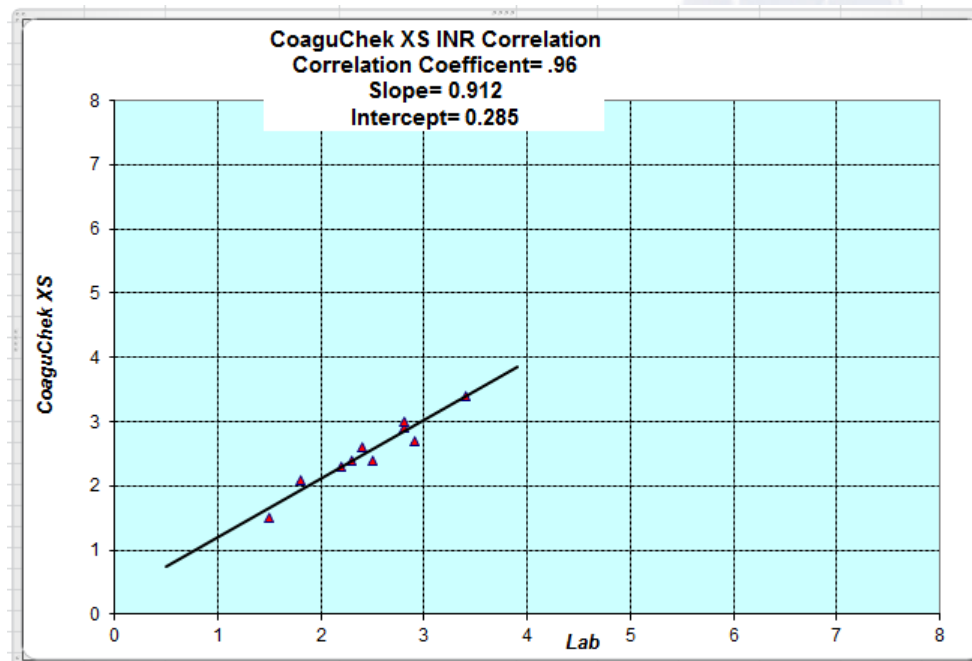
Semiannual Lab Inspections Ambulatory

Checklist based on CAP, TJC and COLA guidelines to include:

- Point of care areas
- Phlebotomy areas
- Specimen collection containers
- Centrifuges and microscopes
- QC logs for every POCT
- Tracking logs
- Refrigerator logs
- Eyewash logs
- Testing supplies in date and marked opened
- Availability of procedures (printed or intranet)
- Competency Checklists/Computer Based Training Modules
- Lab environment
- Record retention

Correlations Ambulatory

- INR
- HBA1c
- Hgb
- Chol
- AST/ALT
- Chem 8



Hospital QA Plan

Details from a Hospital POC QA Plan Moderate Complex Provider Performed Microscopy

Site Visits Hospital

- Some units are visited twice per week
- Waived testing once per month
- Opportunities for improvement easily identified and addressed with frequent site/unit visits
- Establish relationship with testing personnel

Patient Correlations Hospital

- Same analyte with different methodologies
- Same analyte at different sites
- Same analyte with different instruments
- At least once every six months
- Opportunities to identify meters that don't correlate

Patient Tracer Hospital

- Periodic
- Randomly selected patient care areas
- Trace from test result on the POC meter to the patient record (EMR)
- Opportunity to identify clerical or systematic errors

Environmental Rounds Hospital

- Conducted by Health, Safety and Environment Department
- Twice a year
- Unannounced
- Opportunity to identify compliance issues for Institution, local, state or federal regulations
- Corrective action plans are submitted to DHMH

Mock CAP Surveys Hospital

- College of American Pathologists, CAP Standards
- Continuous Quality Improvement (CQI) Office recruits system wide staff volunteers to conduct Mock Surveys
- Corrective Action Plans are submitted to CQI for documentation purposes
- Opportunity to identify and correct issues before CAP inspection

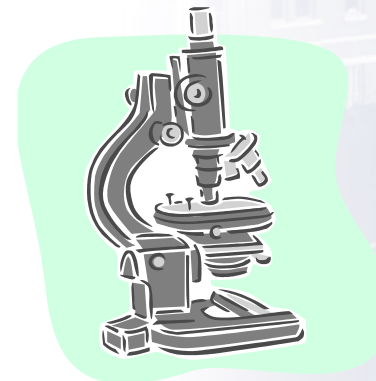
Quality Control Review Hospital

- Monthly review
- Some manual via paper logs
- Some electronic via interface
- Opportunity to identify system trends
- Future: looking at middleware solution for electronic entry and monitoring of all manual POCT

PPM – Provider Performed Microscopy

CLIA Sec. 493.1365 Standard; PPM testing personnel responsibilities.

- Online competency assessment modules completed semi-annually
<http://medtraining.org/>
- Utilized by providers who bill for PPM tests complete these modules





PPM – Provider Performed Microscopy

- Providers, including mid-level providers complete modules
- Initial training
- Annual training once every 6 months
- MTS – reports for completion
- Ability to assign modules for only those tests performed

The Quality Assurance Cycle



Identifying QA Opportunities Ambulatory Sites

- Quality assurance opportunities can be identified by monitoring reports or through other tracked and trended issues
- Develop a corrective action plan for deficits identified
- Monitor the process post-corrective action implementation

Future Growth Hospital Program

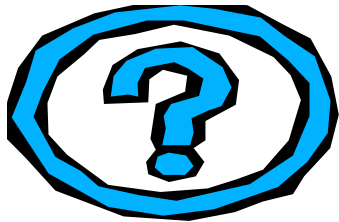
- ❖ Standardized interface platform for Point of Care tests across 5 Hospitals and Ambulatory sites
 - Will allow for quality indicators across the enterprise
- ❖ Standardized electronic medical record
 - Primary care and specialty care access
- ❖ Standardized laboratory information system
 - Harmonized test panels
- ❖ Standardized testing platforms
 - Chemistry and Hematology lines

Summary

A comprehensive Quality Assurance Program includes:

- Continuous Quality Improvement
- Staff training and ongoing competency assessment
- Monitoring program specific to the test(s) performed
- Ongoing quality assurance assessments with appropriate corrective plans and interventions

Questions



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